



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10199 and CMS-10266]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[Insert date 30 days after date of publication in the Federal Register]**:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following

transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-6974 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at
<http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy; Use: We provide coverage for carotid artery stenting (CAS) with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis between 50 percent and 70 percent or have asymptomatic carotid artery stenosis ≥ 80 percent in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1, or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7). Accordingly, we consider coverage for CAS reasonable and necessary (section 1862 (A)(1)(a) of the Social Security Act). However, evidence for use of CAS with embolic protection for patients with high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis ≥ 70 percent who are not enrolled in a study or trial is less compelling. To encourage responsible and appropriate use of CAS with embolic protection, we issued a Decision Memo for Carotid Artery Stenting on March 17, 2005, indicating that CAS with embolic protection for symptomatic carotid artery stenosis ≥ 70 percent will be covered only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. In accordance with this criteria, we consider coverage for CAS reasonable and necessary (section 1862 (A)(1)(a) of the

Social Security Act). Form Number: CMS-10199 (OCN: 0938-1011); Frequency: Yearly; Affected Public: Business or other for-profit and Not-for-profit institutions; Number of Respondents: 1,000; Total Annual Responses: 1,000; Total Annual Hours: 500. (For policy questions regarding this collection contact Lori Ashby at 410-786-6322.)

2. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplants; Use: The Conditions of Participation and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a transplant center qualifies for approval or re-approval under Medicare. We, along with the healthcare industry, believe that the availability to the facility of the type of records and general content of records is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. Form Number: CMS-10266 (OCN: 0938-1069); Frequency: Yearly; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 226; Total Annual Responses: 528; Total Annual Hours: 2,523. (For policy questions regarding this collection contact Diane Corning at 410-786-8486.)

Dated: September 10, 2013

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

[FR Doc. 2013-22329 Filed 09/12/2013 at 8:45 am; Publication Date: 09/13/2013]